

## REMARKS

Claims 27-32 and 48-50 were examined. Claims 27-28 and 49 are amended. Claims 51-53 are added. Claims 27-32 and 48-53 remain in the Application.

The Patent Office rejects claims 27, 31-32 and 48-50 under 35 U.S.C. §102(b). The Patent Office rejects claim 49 under 35 U.S.C. §112, first paragraph. The Patent Office objects to claims 28-30 as dependent upon a rejected base claim. Reconsideration of the pending claims is respectfully requested in view of the above amendments and the following remarks.

### A. 35 U.S.C. §102(b): Rejection of Claims 27-31-32 & 48-50

The Patent Office rejects claims 27, 31-32 and 48-50 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,458,387 of Scott et al. (Scott). Scott is cited for teaching a complexing agent or binding member. Reference is made to column 5, lines 25-34. The complexing agent, according to the Patent Office, is capable of ionic interaction with a therapeutic agent. The Patent Office also finds Scott teaches cleavable molecules attached to an outer surface of a microsphere formed of the complexing agent, citing col. 14, line 61 through col. 15, line 11.

Independent claim 27 is not anticipated by Scott, because Scott does not describe a method including separately delivering a treatment agent and a barrier having a binding member to a tissue. The binding member of the barrier has a property adapted to couple to a surface of the tissue. The barrier is present in an amount sufficient to permit transport of the treatment agent from the tissue at a lower rate than transport in the absence of the barrier component.

Scott describes a microsphere including at least two complexing agents. The complexing agents include a macromolecule such as a carrier protein (e.g., albumin); at least one water soluble polymer (e.g., hetastarch PEG/PVP); a first complexing agent that is an anionic polysaccharide; and a second complexing agent that is a divalent cation. See col. 5, lines 24-37. "[A] complexing agent refers to a molecule which is capable of interacting with a therapeutic agent (discussed below) to facilitate loading, retaining and/or otherwise delaying the release of the therapeutic agent from the microsphere (see, e.g., Table 3)." Col. 5, lines 38-42. Thus, the

complexing agent(s) are intended to bind or otherwise interact with the therapeutic agent or with another complexing agent. See col. 5, lines 54-60. The microspheres including the complexing agent and the treatment agent are prepared ex vivo. See col. 20, line 51 through col. 26, line 11. Scott does not describe separately delivering a treatment agent and a barrier to a surface.

Claims 31-32 and 48-50 depend from claim 27 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 27, claims 28, 31-32 and 48-50 are not anticipated by Scott.

Applicant respectfully requests that the Patent Office withdraw the rejection of claims 27, 31-32 and 48-50 under 35 U.S.C. §102(b).

**B. 35 U.S.C. §112, First Paragraph: Rejection of Claim 49**

The Patent Office rejects claim 49 under 35 U.S.C. §112, first paragraph, because the specification, while enabling for a cationic or an ionic binding member, does not reasonably provide enablement for all binding members.

Applicant respectfully asserts that the Application provides enablement for various types of binding members. For example, at page 8, lines 10-13, a number of binding mechanisms are taught including ionic binding, covalent binding, electrostatic interactions, hydrogen and bonding and the like.

Applicant amends claim 49 to describe the binding member as ionic. Such amendment should not be construed as an acceptance of the Patent Office's argument, but only relates to address an embodiment of a binding member. Applicant respectfully requests that the Patent Office withdraw the rejection of claim 49 under 35 U.S.C. §112, first paragraph.

**C. Objection to Claims 28-30**

The Patent Office objects to claims 28-30 as dependent upon a rejected base claim. Applicant amends claim 28 to incorporate prior claim 27. Applicant respectfully requests that the Patent Office withdraw the objection to claims 28-30.

D. Additional Claims 51-53

Applicant adds claims 51-53. Support for claim 51 may be found in the Application at, page 19, lines 24-25 and page 23, lines 6-13 (Figure 2B). Support for claim 52 may be found in the Application at page 19, lines 25-26 and page 22, line 21 through page 23, line 13 (Figures 2A and 2B). Support for claim 53 may be found in the Application at page 15, lines 16-22.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

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William T. Babbitt  
William Thomas Babbitt, Reg. No. 39,591

12400 Wilshire Boulevard  
Seventh Floor  
Los Angeles, California 90025  
Telephone (310) 207-3800  
Facsimile (310) 820-5988

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Nedy Calderon  
Nedy Calderon

9/11/06

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